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EXAMINER	
CHOI, FRANK I	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/997,663	MEISNER, LORRAINE FAXON	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-8,10-16,18,19 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-8,10-16,18,19 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant does not cite to anywhere in the Specification that supports the claim language "stabilized by physical, non-chemical manipulation". Claims 21-23 are dependent on claim 1 which indicates a pH of 3.5-4.1. The Specification discloses that the pH is adjusted to about 3.7 to about 4.1 to achieve the optimum combination of low irritability and high stability (paragraph 00027), as such, the above limitation excludes the claimed pH range. The claim language in claim 21 does not require pretreatment before adding the ascorbic acid to a composition, whereas, the Specification only discloses the treatment of ascorbic acid at relatively high temperatures to form a concentrated ascorbic acid solution in the context of pretreatment. Claim 23 indicates that the physical, non-chemical stabilization of the ascorbic acids results from an equilibrium reaction between the ascorbic acid and monodehydroascorbic acid. This is a contradiction in terms as it is the presence of a chemical, i.e. monodehydroascorbic acid, that is claimed by the Applicant to result in the stabilization of the ascorbic acid.

Claim 21-23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Applicant only postulates that the observed stability is due to equilibrium reaction between the ascorbic acid and monodehydroascorbic acid without providing any evidence of the same. Even if true, said postulation directly contradicts the limitation that ascorbic acid is stabilized by physical, non-chemical manipulation.

The nature of the invention:

The claims indicate that ascorbic acid is stabilized by physical, non-chemical manipulation.

The state of the prior art and the predictability or lack thereof in the art:

The prior art does not disclose stabilization by physical, non-chemical manipulation.

The amount of direction or guidance present and the presence or absence of working examples:

The Specification does not provide any examples showing stabilization by physical, non-chemical manipulation. In each instance, the stabilization is disclosed to be due to chemical manipulation, i.e. alteration of pH or equilibrium reaction between ascorbic acid and monodehydroascorbic acid. According to the Specification, the dissolution of ascorbic acid in water at relatively high temperature to form a concentration ascorbic acid solution stabilizes the ascorbic acid due to said equilibrium reaction (Specification, paragraphs 00029-00030). The Specification however does not specifically define what is meant by relatively high temperature

and concentration. The description of a "typical" process does not limit the temperature or concentration that can be used. Further, the description only indicates that "It is postulated that the observed stability of the present compositions is afforded by an equilibrium reaction between ascorbic acid and monhydroascorbic acid that maintains a stable solution of ascorbic acid".

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they claim that ascorbic acid is stabilized by physical, non-chemical manipulation. However, only two processes by which stabilization occurs are disclosed by the Specification, both of which require chemical manipulation as indicated above. As such, one of ordinary skill in the art would be required to do undue experimentation in order to determine as to whether there is an equilibrium reaction between ascorbic acid and monodehydroascorbic acid whether the same would result in the stabilization of the ascorbic acid, other physical, non-chemical manipulations that would result in stabilization of the ascorbic acid and what other temperatures and concentrations would constitute relatively high temperatures and concentrations. Further, the phrase "It is postulated" fails to specifically support claim 23 in that there is no indication that an equilibrium reaction between ascorbic acid and monhydroascorbic acid occured or that said equilibrium reaction stabilized the ascorbic acid. See In re Cortright, 49 USPQ2d 1464, 1469 (CAFC 1999) (the court held that the belief that a result occurred without actual observation was not sufficient to support a claim under Section 112, para. 1).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22,23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as follows:

Claim 22 claims that the ascorbic acid is stabilized by dissolution in water at relatively high temperature and concentration. The claim does not indicate what temperature and concentration would be relatively high or otherwise indicate what temperature and concentration would be relatively low. The Specification does not define the same as the temperatures and concentrations disclosed are do not adequately indicate what would constitute relatively low temperatures as the same are prefaced by the terms "typically", "generally" and "about" which indicate non-exclusivity of said disclosed temperatures and concentrations (Specification, paragraphs 00028).

Claim 23 claims that the physical, non-chemical stabilization of the ascorbic acid results from an equilibrium reaction between the ascorbic acid and monodehydroascoribic acid which directly contradicts that limitation that the stabilization be "non-chemical" as the presence of a chemical, i.e. "monodehydroascoribic", is necessary for the stabilization of the ascorbic acid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5-8, 10-16, 18,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinitsky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594), Herstein (US

Pat. 5,902,591), Bassford et al. (US Pat. 2,517,276), Kalus et al., Ptchelintsev (US Pat. 5,972,993) and EP 0 771 557.

Schinitsky et al. teach a composition and method to reduce epidermal wrinkling resulting from photo-aging comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%) and zinc sulfate (about 0.5-5%) in a pharmaceutically acceptable vehicle, for example, hydrophilic lotion, ointment, cream or gel, which is applied once or twice daily (Column 2, lines 38-53, Column 4, lines 34-45, Claims 1, 2). A formulation is disclosed in Table 1 containing among other ingredients, water (58.85 %), glycerine, propylene glycol, zinc sulfate (2.08 %), ascorbic acid (10.06%) and tyrosine and a control formulation is disclosed which contains the same ingredients as set forth in Table 1 except that it does not contain tyrosine or ascorbic acid (Column 3, lines 8-46, Column 4, lines 1-27).

Murad teaches a composition for treatment of skin overexposed to sunlight and wrinkles comprising a sugar, such a N-acetylglucoseamine or glucoseamine, amino acids, such as cysteine, methionine or N-acetyl cysteine, ascorbic acid, and a zinc compound, such as zinc sulfate (Column 4, lines 62-68, Columns 5, 6, Column 7, lines 30-41, Column 9, lines 3-7). It is taught that the composition may be formulated as a cream, paste, gel, ointment, solution or suspension in an aqueous liquid, oil-in-water emulsion or a water-in-oil emulsion by any methods of pharmacy which can be applied topically (Column 8, lines 43-49, Column 9, lines 34-45). It is taught that the sugar and amino acids assist in thickening the dermis and supplementing collagen and elastic tissues which reduces wrinkling and lines (Column 5, lines 5-18). It is taught that the addition of ascorbic acid inhibits collagenase and elastase, enzymes which break down collagen and elastic tissues, and assist in the reducing the occurrence of

additional wrinkles and facilitate the healing of skin tissues (Column 5, lines 18-22). It is taught that zinc binds collagen fibers and inhibits elastase, an enzyme that also breaks down collagen and elastic tissue (Column 5, lines 22-24).

Herstein discloses disclosed that ascorbic acid's activity as anti-oxidant has beneficial pharmaceutical effects with regards to adverse changes in the skin brought about by environmental conditions such as UV exposure but that ascorbic acid is unstable (Column 1, lines 12-68, Column 2, lines 1 –7). It is disclosed that invention in Herstein relates to stable topical cosmetic/ pharmaceutical emulsion compositions containing ascorbic acid and that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule (Column 1, lines 5-11, Column 2, lines 40-47, Column 10, lines 6-17). It is disclosed that the composition contains an organoclay material to stabilize the emulsion, such as aluminum silicate, bentonite, montomorillonite, fuller's earth, attapulgite, hectorite and (Column 3, lines 1-44). It is disclosed that that anti-inflammatories can be added to provide added photoprotection, especially from UV (Herstein, Column 9, lines 54-56).

Bassford et al. disclose methods of purifying ascorbic acid in which one of the steps includes dissolving ascorbic acid in distilled water at 60 degrees Celsius, for example 105 g in 140 cc, 100 g in 140 cc, 30 g in 30 cc (Column 4, lines 16-33, Column 5, lines 60-76, Columns 6-8). It is disclosed that when preparing pharmaceutical compounds it is generally advisable to effect the final purification by crystallizing a first crop of pure material in the conventional manner that is disclosed as being Experiment B (Column 3, lines 30-35, Column 5, lines 60-68, Column 6, lines 39-76, Column 7).

Kalus et al. disclose that ascorbic acid will form semidehydroascorbic acid in the presence oxygen and/or metals (Abstract).

Ptchelintsev discloses that topical application of an antioxidant, such as ascorbic acid, is effective in reducing the redness, flushing and blushing associated with either sensitive skin or rosacea (column 4, lines 35-56). It is disclosed that the amount of antioxidant can range from 0.001 wt% to about 100wt% but that for practical reasons creams, emulsions, lotions or gels would require concentrations of antioxidants that are less than 50 wt% (Column 6, lines 49-68).

EP 0 771 557 discloses the use of ascorbic acid, preferably in the amount of 1 to 20% by weight, for treatment of acne, preferably at a pH of 2 to 5, particularly at a pH of 4 (Page 2, lines 30-58, Page 3, lines 1-7).

The prior art discloses topical compositions containing ascorbic acid, zinc sulfate and water. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of at least 10% of ascorbic acid, amino-sugar, water and pH of 3.5 to 4.1. However, the prior art amply suggests the same as the prior art discloses the combination of ascorbic acid and amino-sugar, the use of ascorbic acid up to 20% and that a pH of 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin. Also, the prior art discloses that ascorbic acid is effective in the treatment of rosacea, acne and hypersensitivity conditions. Further, the prior art discloses the preparation of pure ascorbic acid for pharmaceutical use in which one of the steps includes dissolving ascorbic acid in water at 60 degrees Celsius. Furthermore, the prior art discloses that semidehydroascorbic acid results from the reaction of ascorbic acid with oxygen and/or metals. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art

as above with the expectation that the same would facilitate entry of ascorbic acid into the skin and that the combination would be effective in treating or protecting against skin damage due to exposure to the sun. Further, one of ordinary skill in the art would be motivated to prepare the ascorbic acid according to the process in Bassford with the expectation that the product would sufficiently pure for pharmaceutical purposes. Further, one of ordinary skill in the art would have been motivated to use clays with the expectation that in emulsion preparations that the clay would stabilize the emulsion. Furthermore, one of ordinary skill in the art would expect that once the ascorbic acid is exposed to oxygen and/or metals that semidehydroascorbic acid would be present in the composition. Finally, one of ordinary skill in the art would have expected that the ascorbic acid would be effective in topically treating rosacea, acne and hypersensitivity conditions.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive for the reasons of record and the further reasons below.

Contrary to the Applicant's arguments, the "prima facie" statement is a conclusion statement it is not the motivation statement. In any case, there is no requirement that the prior art provide a specific motivation to combine and/or modify the prior art. See KSR International Co. v. Teleflex Inc. 550 U.S. ___ (2007) (Slip Opinion, No. 04-1350, April 30, 2007). Further, the Examiner has set forth the reasons to combine and/or modify the references in the statements prior to said "prima facie" statement.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re*

Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

The Applicant acknowledges that Schinitsky et al. teaches the combination of tyrosine (an amino acid), ascorbic acid and a non-toxic zinc salt (Reply (2/13/2007), page 7). The Applicant then argues that one of ordinary skill in the art having only Schinitsky before would have to go through a convoluted multistep procedure. The Applicant provides no evidence and no caselaw that supports that one of ordinary skill in the art would be required to go through this procedure. In the first instance, one of ordinary skill in the art is presumed to have full knowledge of the prior art in his field of endeavor and the ability to select and utilize knowledge from analogous arts (See Lamont v. Berguer, 7 USPQ2d 1580, 1582 (Bd.Pat. Ap. & Int. 1988). The Applicant provides no reason why Schinitsky's teachings of ascorbic acid percentages of 2% to 10% would have to be disregarded in view of the fact that the disclosed 10% reads on the claimed amount of 10% in claim 1. Further, the combined teachings of the prior art, as indicated above, disclose and/or suggest that amounts of ascorbic acid greater than 10% are effective in treating acne, redness and rosacea. The Applicant provides no reasoning as why of one of ordinary skill in the art would have spontaneously assume, without prompting, that pH values of a composition should be of importance when Herstein, as indicated above, discloses the importance of pH. The Applicant provides no reasoning why Schinitsky's teaching of the

necessity of zinc sulfate would have to be disregarded when the claims do not exclude zinc sulfate. The Applicant provides no reasoning why one of ordinary skill in the art would have to spontaneously assume that the composition needs an amino sugar when Murad, as indicated above, provides reasons for including aminosugars.

Applicant argues that in Murad ascorbic acid must be used in combination with amino acids, however, Applicant's claims do not exclude the use of amino acids. Applicant cites to various preferred examples or embodiments, however, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 169 USPQ 423 (CCPA 1971).

Applicant argues that Murad does not teach or suggest ascorbic acid be used in absence of at least one transition metal, such as zinc. However, Applicant's claims do not exclude the use of transition metals or zinc. Further, there is no requirement that Murad disclose a pH of between 3.5 and 4.1. Furthermore, the Applicant provides no reason why the ascorbic acid percentages of 5% to 10% would have be disregarded when 10% reads on the claimed amount of 10%. As indicated above, amounts of ascorbic acid greater than 10% are also disclosed or suggested by the prior art for the treatment of acne, redness and rosacea. Also, Murad, as indicated above, discloses the benefits of ascorbic acid and sugars, as such, one of ordinary skill in the art would have been motivated to combine the same with the expectation that the combination would exhibit the disclosed benefits. As such, as with the Schinitsky reference, the Applicant's convoluted procedure is neither required by the claims nor the caselaw.

The Applicant provides no reason why one of ordinary skill in the art would have to disregard all of Herstein's teachings of usefulness or desirability of other ingredients in view of

the fact that the Applicant's claims are open to addition of other ingredients. The Applicant provides no reason why one of ordinary skill in the art could not select the teaching of Herstein with respect to pH in view of the fact that Herstein discloses that the pH facilitates absorption of ascorbic acid into the skin or why one of ordinary skill in the art would have to selectively cull said teaching. The Applicant provides no reasoning why one of ordinary skill in the art would not be able to adjust compositions to have a pH of 3.5 to 4.1 in view of the fact the prior art discloses pHs of compositions in said range.

The Examiner has set forth the reasons for combining and/or modifying the prior art as indicated above. Clearly, one of ordinary skill in the art having knowledge of chemistry, biology and pharmaceutical sciences, would understand from the prior art the effects of UV radiation on the skin, including wrinkling and inflammation, the effectiveness of ascorbic acid on treatment of the same as well the use of ascorbic acid to treat other skin inflammations, such as acne and rosacea. Further, one of ordinary skill in the art would understand that other active agents can be combined with the ascorbic acid, such as aminosugars, including glucosamine, to assist the ascorbic acid in treating the skin. Finally, one of ordinary skill in the art would understand that a pHs falling within the claimed range would increase the effectiveness of ascorbic acid by facilitating entry of the ascorbic acid in the skin. As indicated above, the Applicant's convoluted steps of that one of ordinary skill in the art would be required to do to arrive at the claimed invention neither warranted by the caselaw or teachings of the prior art. See KSR v. Teleflex, Slip Opinion at pages 14, 17 (the inferences and creative steps that a person of ordinary skill in the art would employ can be taken into account; one of ordinary skill in the art is not an automaton).

With respect to claims 5, 7, 11, 13-16, 19, the Applicant provides no argument except to indicate claim differentiation. Said argument fails to indicate how the claims avoid the prior art, as such, the rejection over said claims is maintained.

With respect to claim 6, the examiner deems the argument moot that there is no disclosure or suggestion of monodehydroascorbic acid in the cited references in view of newly cited art, Kalus et al.. As indicated above, monodehydroascorbic acid will be present in the prior art composition by virtue of exposure of the ascorbic acid contained in said composition to oxygen and/or metals.

With respect to claims 8 and 18, the Applicant argues that the cited prior art does not disclose topical treatment of inflammatory skin conditions. However, the prior art does disclose treatment of UV exposure. The Applicant provides no evidence that inflammatory skin conditions exclude skin exposed to UV. Further, Herstein specifically discloses that anti-inflammatories can be added to provide added photoprotection, especially from UV (Herstein, Column 9, lines 54-56).

With respect to claim 10, Murad does not teach away from glucosamine in the amount of approximately 20% (w/v). In the first instance, the amounts disclose in Murad are merely preferred amounts (Murad, column 4, lines 1-15). In the second instance, the Applicant provides no evidence that about 17% excludes approximately 20%. Finally, it would be well within the skill of and one of ordinary skill in the art would expect that amounts of glucosamine contained in the composition can be varied, including the amounts claimed, as desired depending on effectiveness on treating the skin condition and severity of the same.

With respect to claim 12, the Examiner deems the Applicant's argument that the prior art does not teach the inflammatory conditions listed in claim 12 moot in light of the teachings of EP 0 771 557 and Ptchelintsev. As such, one of oridinary skill in the art would expect that the prior art composition would be effective in the treatment of inflammatory skin conditions, such as acne and rosacea.

The Applicant declines to address Bassford.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1, 5-8, 10-16, 18,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinitsky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594), Darr et al. (US Pat. 5,140,043), Bassford et al. (US Pat. 2,517,276), Yue et al. (US Pat. 5,700,451), Kalus et al., Ptchelintsev (US Pat. 5,972,993) and EP 0 771 557.

Schinitsky et al. is cited for the same reasons as above and incorporated herein to avoid repetition.

Murad is cited for the same reasons as above and incorporated herein to avoid repetition.

Darr et al. disclose that ascorbic acid's activity as anti-oxidant has beneficial pharmaceutical effects with regards to adverse changes in the skin brought about by environmental conditions such as UV exposure but that ascorbic acid is unstable (Column 1, Column 2, lines 1 –55). It is disclosed that a pH of no more than about 3.5 ensures that greater than 82% of the ascorbic acid remains in the protonated, uncharged form and facilitates entry of ascorbic acid into the skin and stabilizes the ascorbic acid molecule (Column 3, lines 17-33,

Column 4, lines 7-18, claims 1-42). It is disclosed that at even at a pH of 4.5, a 5% solution of ascorbic acid remains quite stable and that at a pH of 4.2, 5% ascorbic acid remained stable (Column 5, lines 1-27). It is disclosed that carriers for topical application useful in practicing the invention include but are not limited to alkylene glycols, such as propylene glycol, or alkylene glycols in combination with hydroxyalkylcellulose derivatives, such as hydroxypropylcelulose, and glycerol (Column 3, lines 33-53). It is disclosed that ascorbic acid can be present in amounts of at least about 1 wt. %, preferably from about 3 to 20 wt.%, and more preferably about 5 to 10 wt.% in water and a carrier for topical application (Column 3, lines 18-33).

Bassford et al. is cited for the same reasons as above and is incorporated herein to avoid repetition.

Yue et al. disclose the use of titanium dioxide as a topical sunscreen which can be incorporated into solutions, lotions, creams, ointments, skin cosmetics and the like and emulsions (Column 5, lines 13-44). It is disclosed that the compositions can include colorants and finishing agents which provide a pleasing color and/or additional suncreeen activity, such as talc, mica, magnesium carbonate, calcium carbonate, magnesium silicate, silica, zinc oxide, red iron oxide, etc. (Column 7, lines 60-68, Column 8, lines 1-14). It is disclosed that the compositions can include anti-oxidants/radical scavengers such as ascorbic acid (Column 12, lines 20-28).

Kalus et al., Ptchelintsev (US Pat. 5,972,993) and EP 0 771 557 are cited for the same reasons as above and is incorporated herein to avoid repetition.

The prior art discloses topical compositions containing ascorbic acid, zinc sulfate and water. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of at least 10% of ascorbic acid, amino-sugar, water and

pH of 3.5 to 4.1. However, the prior art amply suggests the same as the prior art discloses the combination of ascorbic acid and amino-sugar, the use of ascorbic acid up to 20% and a pH of about 3.5 and that at pHs of 4.2 and 4.5, a 5% solution of ascorbic acid remained stable. Further, the prior art discloses that ascorbic acid is effective in the topical treatment of rosacea, acne and hypersensitivity conditions. Furthermore, the prior art discloses that semidehydroascorbic acid results from the reaction of ascorbic acid with oxygen and/or metals. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that a solution of ascorbic acid at a pH of about 3.5 would be stable and that the combination would be effective in treating or protecting against skin damage due to exposure to the sun as well as other inflammatory skin diseases, including rosacea, acne and hypersensitivity. Further, one of ordinary skill in the art would be motivated to prepare the ascorbic acid according to the process in Bassford with the expectation that the product would sufficiently pure for pharmaceutical purposes. Further, one of ordinary skill in the art would have been motivated to use titanium dioxide with the expectation that the same would assist in inhibiting the adverse effects of UV exposure through its sunscreening activity. Furthermore, one of ordinary skill in the art would have expected that the composition would contain semidehydroascorbic acid as the ascorbic acid in the composition is exposed to oxygen and/or metals.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive for the reasons above and the further reasons below.

The Applicant makes the general note that the disclosure in Darr that transition metal ions catalyze oxidative degradation would appear to teach away from the combination with Murad

that discloses the necessity of a transition metal component. However, the Applicant provides no evidence that Darr excludes the use of transition metals. Further Murad specifically indicates that ascorbic acid is suitable for use in the composition in Murad as indicated above. As such, in light of the teachings of the prior art above, including teachings as to the benefits of metals, such as zinc, one of ordinary skill in the art would have a reason to use ascorbic acid in combination with metals, such as zinc, notwithstanding any possible degradation if the ascorbic acid due to the presence of transition metal ions.

The Applicant declines to address Bassford, Darr and Yue.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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